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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/715,730

11/18/2003

George F. Fattman

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CONVATEC INC.

100 HEADQUARTERS PARK DRIVE

SKILLMAN, NJ 08558

EXAMINER

CHAPMAN, GINGER T

ART UNIT

PAPER NUMBER

3761

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/715,730	<b>Applicant(s)</b> FATTMAN, GEORGE F.	
	<b>Examiner</b> Ginger T. Chapman	<b>Art Unit</b> 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-18,21 and 22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-18,21 and 22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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## **DETAILED ACTION**

### ***Status of the claims***

1. Claim 1 is amended, claim 22 is added; claims 1-3 and 5-18 and 21-22 are pending in the application.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1, 3, 5-18 and 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Doyle (US 4,551,490) in view of Steer et al (GB 1,571,657) in view of Hahn et al (US 3,983,298) and further in view of (Lloyd (US 4,475,908).

5. With respect to claims 1 and 21, Doyle teaches an adhesively coupleable ostomy device (c. 1, l. 10, c. 2, l. 31 & ll. 41-44) comprising a pressure sensitive adhesive (c. 2, l. 8), said adhesive, and thus any adhesive interface, comprising silicate resin including their blends and

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reaction products (c. 1, l. 68; c. 4, l. 55), said adhesive being resistant to migration of stomal fluids into adhesive interface (c. 2, ll. 31-34

6. With respect to the limitation that the ostomy device is a two component device, Doyle, at c. 6, ll. 13-19, teaches that the pressure sensitive adhesive is suitable as skin barriers for ostomates, and additionally teaches that the adhesive is suitable for attaching a coupling element could be attached to the polymeric surface of a two-part ostomy device as taught by Steer. Doyle does not expressly incorporate the device of Steer, but teaches the adhesive of Doyle is suitable for the known, prior art two part ostomy device of Steer. The prior art ostomy device of Steer is a two component adhesively coupleable ostomy device, suitable for pressure sensitive adhesive coupling. Steer, at page 1, lines 15-20, and as best depicted in Figures 1-6, provides motivation for a secure coupling between the two components (14, 16) of a two component adhesively coupleable ostomy device (p. 2, ll. 100-110) said two components (14, 16) releasably coupled to one another along an adhesive (78) interface. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply the pressure sensitive adhesive of Doyle to the two component adhesively coupleable device of Steer since Doyle teaches its suitability for this purpose and Steer states at c. 1, ll. 15-20 that the benefit of such coupling is that it provides secure coupling thereby preventing leakage, while allowing the bag to be easily removed and replaced thereby providing a more sanitary and convenient device for the consumer.

7. Doyle in view of Steer discloses the claimed invention except for one or more polysiloxanes. Hahn, at c. 1, ll. 64-65, teaches the suitability of polysiloxanes in pressure sensitive adhesives. Therefore it would have been obvious to one having ordinary skill in the art

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to utilize the polysiloxanes as taught by Hahn in the adhesive composition of Doyle since Hahn states, at c. 1, ll. 63-65, that the benefit of using polysiloxanes is that they provide high tack, good adhesive strength and excellent resistance to creep.

8. The combination of Doyle, Steer and Hahn disclose the claimed invention except one of the components having a closed cell foam surface. As best depicted in Figures 1 and 2, Lloyd teaches an ostomy device having a closed cell foam surface 3 and the adhesive interface 4 being coated onto foam surface 3. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to form one of the components of Doyle comprising foam surface as taught by Lloyd since Lloyd states, at c. 2, ll. 4-6 and ll. 13-17, that the benefit of such is that it forms a resilient spacer which conforms to the skin and movements of the wearer between the skin of the wearer and the an ostomy bag in order to reduce skin irritation.

9. With respect to claim 3, Doyle teaches the adhesive, and thus any adhesive interface, includes between about 5% and about 65% hydrocolloids (c. 4, ll. 9-10).

10. With respect to claim 5, Doyle discloses the claimed invention except for one or polysiloxanes. Hahn teaches polyorganosiloxanes and diorganosiloxanes (c. 4, l. 45) suitable for pressure sensitive adhesives. Hahn, at c. 1, ll. 64-65, teaches the suitability of polysiloxanes in pressure sensitive adhesives. Therefore it would have been obvious to one having ordinary skill in the art to utilize the polysiloxanes as taught by Hahn in the adhesive composition of Doyle since Hahn states, at c. 1, ll. 63-65, that the benefit of using polysiloxanes is that they provide high tack, good adhesive strength and excellent resistance to creep (see claim 1, *supra*).

11. With respect to claim 6, Doyle teaches plasticizing oil (c. 3, ll. 38-43).

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12. With respect to claim 7, Doyle discloses the claimed invention except for the plasticizing oil is polydimethylsiloxane. Hahn teaches polydimethylsiloxane (Example 3, col. 12, ll. 49-52).

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the adhesive of Doyle comprising polydimethylsiloxane as taught by Hahn for the benefits of tack and adhesive strength taught by Hahn (Table 1, col. 12, ll. 29-44).

13. With respect to claims 8 and 9, Doyle discloses the claimed invention except for the polysiloxanes blended, treated or reacted with one or more silicate resins comprising trimethylsiloxy silica. Hahn, at Example 1 & Example 2, teaches trimethylsiloxy (c. 11, ll. 49-50 & c. 12, ll. 5-12). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize the silicate resins of Hahn in the composition of Doyle for the beneficial pressure sensitive adhesive properties taught by Hahn in Table 1.

14. With respect to claim 10, Doyle teaches the adhesive, and thus any adhesive interface, includes material having silanol functionality (c. 4, l. 55).

15. With respect to claims 11 and 15, Doyle discloses the claimed invention except for ratios of silicate to polysiloxanes and percentages of plasticizing component. Doyle, at c. 5, ll. 3-9, teaches that by adjusting the percentages of the components of the adhesive composition, properties such as duration of adhesion, resistance to erosion from biological fluids, stretchability, and removal without skin stripping can be varied according to the particular intended end use of the adhesion including, *inter alia*, for an ostomy device. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to form the composition with the claimed percentages since it has been held that discovering an optimum

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value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

16. With respect to claims 12 and 13, Doyle teaches further property modifiers including tackifier (c. 4, l. 20) and silicate (c. 4, l. 55).

17. With respect to claim 14, Doyle teaches the adhesive, and thus the adhesive interface, contains a medicament for treatment or protection of peristomal skin (c. 4, l. 40-46; c. 5, ll. 8-10).

18. With respect to claims 16 and 17, Doyle discloses the claimed invention except for peel strength from a polyethylene or ethylene copolymer film between 0.5 and 9.0 Newtons/inch using the test method ASTM D3330 wherein the stainless steel substrate is replaced by polyethylene or ethylene copolymer film. Doyle, at c. 6, ll. 13-19, teaches the adhesive is intended for adhesion to a polymer film substrate of a two part ostomy device such that the ostomy coupling element can be attached to the polymeric film substrate of the adhesive interface; i.e. a two component adhesively coupleable ostomy device which is releasably coupled along the adhesive interface between the two components (see claim 1, *supra*). Doyle further teaches the adhesive is resistant to migration of stomal fluids (c. 2, ll. 21-22). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to form the adhesive having the claimed range of properties since it has been held that if a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim. *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997).

19. With respect to claim 18, Doyle discloses the claimed invention except for the adhesive has a coat weight between about 10 grams/square meter and about 150 grams/square meter.

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Optimization of ranges of parameters within prior art ranges or through routine experimentation is not sufficient to patentably distinguish the invention over the prior art. MPEP § 2144.05. One of ordinary skill in the art would have recognized that increasing the thickness, and therefore the coat weight of the adhesive interface, would increase the adhesive strength joining the components, while reducing the coat weight would reduce the thickness of the coat resulting in less cost or bulkiness. One of ordinary skill in the art would have recognized the benefit of optimizing the adhesion of the components depending on their function and exposure to body fluids. Therefore the parameters of coat weight and thickness are result effective variables and as such, it would have been obvious to optimize them. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

20. With respect to claim 22, the combination of Doyle, Steer, Hahn and Lloyd discloses the claimed invention except discloses the claimed invention except for the foam is a copolymer of ethylene and vinyl acetate. The combination of Doyle, Steer, Hahn and Lloyd provide motivation for a layer that cushions and protects the skin around the stoma thus providing motivation for such. Foam comprising a copolymer of ethylene and vinyl acetate is well known in the art as EVA commonly used for cushioning in articles of clothing. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the foam of Doyle/ Steer/ Hahn / Lloyd as EVA foam since Lloyd states, at c. 1, l. 25, that plastic foams capable of moisture vapor transmission are suitable foams, EVA foam is plastic foam capable of vapor transmission and thus falls into the genus of plastic foams taught by the prior art and therefore would be obvious for the benefits Lloyd discloses and since it has been held to



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be within the general skill or a worker in the art to select a known material on the basis of its suitability for the intended use. *In re Leshin*, 125 USPQ 416.

***Response to Arguments***

21. Applicant's arguments with respect to claims 1-3, 5-18 and 21-22 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

22. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginger T. Chapman whose telephone number is (571)272-4934. The examiner can normally be reached on Monday through Friday 9:30 a.m. to 6:00 p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ginger T Chapman/

Examiner, Art Unit 3761

02/10/09

/Tatyana Zalukaeva/

Supervisory Patent Examiner, Art Unit 3761